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| 10/812,380 | 03/29/2004 | Ifrikhar Khan | 1800-000001 | 2606 |
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| 02/24/2009 | | | | |
| EXAMINER | | | | |
| DEAK, LESLIE R | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/812,380

Applicant(s)

KHAN ET AL.

Examiner

LESLIE R. DEAK

Art Unit

3761

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 26 November 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-20.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Applicant's arguments are directed to the claims as amended, and the amendment has not been entered. Nonetheless, the Examiner wishes to address Applicant's arguments that may become important upon appeal. See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: Drawing submitted on 26 January 2009 is not entered.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761

Continuation of 3. NOTE: The amendments to the claims materially affect the scope of the claims, and require new search and consideration. Accordingly, the amendment is not being entered.

Applicant argues that the Examiner is not "one of ordinary skill" in the art, since one of ordinary skill should be one who has actually used the claimed devices. The Examiner notes that she has not, in fact, indicated that she herself is a person of "ordinary skill" in the art. A person of "ordinary skill" is a hypothetical person who is presumed to have known the relevant art at the time of invention. See MPEP §2141.03. The hypothetical person is not necessarily definable by way of credentials as asserted by Applicant. The Examiner's job is to ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984). In the instant case, it is the position of the Examiner that a person having ordinary skill in the art would have known about the inventions disclosed by Squitieri, Parks, Trerotola, and Twardowski and would have looked to the teachings of those references to solve design problems found in existing arteriovenous shunts.

The listing of references in the arguments is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Rejections under 37 CFR 1.83(a):

Applicant argues that the claimed cuff does not have a "graded" inside diameter and the drawing objection should be withdrawn. However, the Examiner notes that Claim 1, line 16 specifically claims that "said cuff defines a graded inside diameter." Since the element is presented in the claims, it is required to be shown in the drawings.

Rejections under 35 USC 103:

Applicant argues that there is no motivation to combine the teachings of Squitieri and Parks, since Squitieri teaches a hemodialysis shunt, and Parks teaches a gastronomy tube. The Examiner respectfully disagrees. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner relies on the Parks reference to teach a connector that connects two fluid conduits, which is analogous to both the concept of fluid transfer in Squitieri and Applicant's invention. One of ordinary skill in the art would be motivated to look to connectors in fluid transfer devices to provide a connector for the fluid transfer device disclosed by Applicant.

Applicant argues that Squitieri does not disclose that the venous outflow catheter is passed into the right atrium. However, Squitieri illustrates that the catheter is placed in what a person of ordinary skill in the art would recognize as the jugular vein, tunneled to what one of ordinary skill in the art would recognize as the vena cava and to the right atrium (see Squitieri FIG 9). As such, the Squitieri apparatus is "configured to," or of an appropriate size and shape to be deployed in the location claimed by applicant. Applicant argues that it is unreasonable to suggest that Squitieri's catheter can be advanced to the right atrium because the reference does not mention the names of the veins in which the apparatus is deployed. However, an analysis of obvious "need not seek out precise teachings directed to the specific subject matter of the challenged claim." *KSR v. Teleflex Inc.* 127 S.Ct. 1727, 1741 (2007). The fact-finder may take account of the inferences and creative steps that a person of ordinary skill in the art would employ. *Id.* As such, it is not necessary that Squitieri name the veins in which the venous return catheter is placed, especially since the reference illustrates that the catheter is placed in what one of ordinary skill in the art would recognize as the jugular vein, extending into the vena cava towards the right atrium. Accordingly, the instantly claimed apparatus is unpatentable over the disclosures of Squitieri and Parks. Applicant further argues that modification of the disclosure of Squitieri "shall lead to invalidation of his patent." The Examiner notes that modification of prior art references does not render a patent invalid under 35 USC 101, 102, or 103. Every patent is presumed to be valid. See 35 USC 282. Outside of reexamination proceedings, the question of validity or invalidity is exclusively a matter to be determined by a court. Likewise, the question of enforceability or unenforceability is exclusively a matter to be determined by a court. See MPEP § 1701

Applicant argues that the instantly claimed invention functions differently than the applied prior art. The Examiner notes that this may be the case. However, the cited prior art is relied upon not to teach an overall principle of operation, but rather to illustrate that one having ordinary skill in the art at the time of invention would know of the elements for which each reference was cited.

Applicant argues that the disclosures of Trerotola and Twardowski are similar to that of Squitieri, and should have been used applied to Squitieri's invention. The Examiner notes that the prosecution of prior cases has no bearing on the prosecution of the instantly presented claims, which are prosecuted independently of the prior art.